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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,419	02/12/2002	Takanari Tominaga	1422-0514P	1153

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,419	TOMINAGA ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,37,38 and 61-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,37,38 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 33 and 37 have been amended. Claims 34-36, 39-44, and 49-60 have been canceled. New claims 61-63 have been added. Any rejection or objection not specifically repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 38, and 61-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most of the diseases recited, does not reasonably provide enablement for anemia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;

(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

The claims have been amended from methods of treating generic diseases requiring production of NO or regulation of cytokine production, to a list of specific diseases having various and somewhat overlapping etiologies. McCaffrey et al (Biochem. Biophys. Res. Comm., 1992) teaches that fucoidan increases the activity of TGF–β, and this increase is beneficial in some diseases. See abstract and Introduction. Song et al (J. Clin. Invest., 1998) also discusses the role of this cytokine in controlling autoimmune and inflammatory pathologies. However, an increase in TGF-b can produce anemia as a side effect. See "Introduction." Therefore, one of ordinary skill would deduce that a systemic rise in TGF–β or an increase in its activity (as would be the case in the administration of fucoidan) would likely exacerbate anemia rather than ameliorate it. The specification provides data showing the effect of various cytokines, but there is nothing demonstrating the effective treatment of anemia. Therefore, one of ordinary skill would require undue experimentation at great expense in terms of time and cost to use this invention commensurate with the scope of the claims.

Claim Rejections - 35 USC § 103

Claims 33, 37, and 38 are again rejected under 35 U.S.C. 103(a) as being unpatentable over SAKAI et al (WO 96/34004) and LION CORP (JP 11-21247), as set forth in the previous Office action. Newly added claims 61-63 are included in this rejection.

The claims have been amended as set forth above. Newly added claims are drawn to methods of administration with limitations that were previously recited in canceled claims and addressed in the previous Office action.

Applicant's arguments filed November 5, 2004 have been fully considered but they are not persuasive.

Applicant argues that LION teaches away from using the fucoidan recited in the claims because some of the fucoidans tested by LION have lower activity in tests used as models for treatment of allergic disorders. However, the vast majority of the fucoidans tested have high activity. Therefore, one of ordinary skill would reasonably expect, that is, it would be more likely than not, that the fucoidan disclosed by SAKAI would also have high activity in these tests and have utility in the treatment of allergies.

Applicant also states that examples 7 and 8 of the present example demonstrate that IgE antibody titer is suppressed by administration of the specific recited fucoidan. This is noted, and it may be that this activity is specific to this particular fucoidan, but there is no comparison with any other fucoidan, so this cannot be determined. It is further noted that when comparisons are shown (see example 6), the fucoidan of the invention has similar activity with the fucoidan derived from *Fucus vesiculosus*, one of LION's preferred fucoidans.

Claims 33, 38, and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAKAI et al (WO 96/34004) and McCAFFREY et al (Biochem. Biophys. Res. Comm., 1992) in view of GRAINGER et al (US 6,117,911).

The claims have been amended as set forth above.

SAKAI teaches as set forth in the previous Office action.

MCCAFFREY teaches as set forth in the previous Office action. The reference further teaches that fucoidan binds to and increases the activity of TGF–β and suggests the use of fucoidan in immunosuppression. See especially abstract, introduction, and last paragraph of reference.

These references do not teach the treatment of autoimmune disease, generically, or the specific diseases that are variously classified as autoimmune or inflammation-related diseases.

GRAINGER teaches that decreased level of TGF–β is implicated in atherosclerosis, as discussed by McCaffrey. See col 1, lines 44-48. The reference further teaches that agents that maintain or elevate TGF–β levels have utility in the treatment of autoimmune and inflammation-related diseases. See the paragraph bridging col 1-2.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer any known therapeutically useful fucoidan such as that disclosed by SAKAI for the treatment of autoimmune or inflammation-related diseases. One of ordinary skill would be motivated to provide such treatment because MCCAFFREY had taught that fucoidan increases the activity of endogenous TGF–β. This increase in activity would be essentially equivalent to elevating the level of TGF–β, which GRAINGER had taught is useful in treating such diseases. Therefore, one of ordinary skill would reasonably expect success with such treatment. It would be within the scope of the artisan to administer the fucoidan by any common method.

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
January 21, 2005

JAMES O. WILSON
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